Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

Comparison of the Effectiveness of routine Physiotherapy and Rehabilitation with Periarticular Prolotherapy with Dextrose in Patients with Rotator Cuff Tendonitis

Protocol summary

Study aim
Comparison of the Effectiveness of routine Physiotherapy and Rehabilitation with Periarticular Prolotherapy with Dextrose in Patients with Rotator Cuff Tendonitis

Design
Clinical trial with control group,parallel group trial with single blinded outcome assessment, Randomised

Settings and conduct
The clinical trial is done at Tehran-Emam Reza Hospital, Patients with Rotator Cuff Tendonitis are randomisedly divided into two groups of intervention (Periarticular Prolotherapy with Dextrose 12.5%) and control (physiotherapy).Outcome assessments based on the Visual scale of pain (VAS)and the Shoulder Pain and Disability Index (SPADI) questionnaire are performed before the intervention, one week and one month later.The study is single blind and result's evaluator is kept blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria:Patients aged 18-65 years with Rotator Cuff Tendonitis; Exclusion criteria:Patients with malignancy or Diabetes mellitus or complete rotator cuff tear

Intervention groups
Intervention group: Periarticular Prolotherapy with Dextrose 12.5% and control; group: physiotherap for Rotator Cuff Tendonitis

Main outcome variables
Visual scale of pain;Pain and disability severity based on Shoulder Pain and Disability Index questionnaire

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181217042028N1**
Registration date: **2019-04-13, 1398/01/24**
Registration timing: **retrospective**

Last update: **2019-04-13, 1398/01/24**
Update count: **0**

Registration date
2019-04-13, 1398/01/24

Registrant information

Name
Fatemeh Abdorrazaghi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 6652 1827

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-01-31, 1397/11/11

Expected recruitment end date
2019-02-19, 1397/11/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the Effectiveness of routine Physiotherapy and Rehabilitation with Periarticular Prolotherapy with Dextrose in Patients with Rotator Cuff Tendonitis

Public title

Effect of Periarticular Prolotherapy with Dextrose in Patients with Rotator Cuff Tendonitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with Rotator Cuff Tendonitis

Exclusion criteria:
History of Diabetes Mellitus History of Malignancy Complete rotator cuff tear

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **2**
One or two shoulder

Randomization (investigator's opinion)
Randomized

Randomization description
Blocked randomization

Blinding (investigator's opinion)
Single blinded

Blinding description
Result's evaluators are kept blind.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee AJA University of Medical Sciences

Street address
Emam Reza hospital, Etemad zade Ave, West Fatemi Ave

City
Tehran

Province
Tehran

Postal code
1411718541

Approval date
2018-12-23, 1397/10/02

Ethics committee reference number
IR.AJAUMS.REC.1397.069

Health conditions studied

1

Description of health condition studied
Rotator Cuff Tendonitis

ICD-10 code
M75.11

ICD-10 code description
Incomplete rotator cuff tear or rupture not specified as traumatic

Primary outcomes

1

Description
Pain and disability severity based on Shoulder Pain and Disability Index questionnaire

Timepoint
Before the intervention, one week and a month later

Method of measurement
Shoulder Pain and Disability Index questionnaire

2

Description
Pain severity based on Visual Analogue Scale

Timepoint
Before the intervention, one week and a month later

Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Periarticular Prolotherapy with 12.5 % Dextrose

Category
Treatment - Drugs

2

Description
Control group: Physiotherapy and Rehabilitation(10 Sessions)

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Reza hospital
Full name of responsible person
Zahra Rezasoltani
Street address
Emam Reza hospital, Etemad zade Ave, West Fatemi Ave
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Mostafa Shahrezai
Street address
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Artesh University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Zahra Rezasoltani
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Physical Medicine
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Person responsible for updating data

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Resident
Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only part of the data, such as information on the main outcome, can be shared.

When the data will become available and for how long

6 months after printing the results

To whom data/document is available

Only available to scholars working in universities and academia.

Under which criteria data/document could be used

Only for doing research

From where data/document is obtainable

You can contact Zahra Rezasoltani by e-mail to z.rezasoltani@ajaums.ac.ir.

What processes are involved for a request to access data/document

His/her request must first be submitted to the Physical Medicine and Rehabilitation Department of the Army Medical University.If approved, the legal process should be continued through the relevant authorities at the university.

Comments